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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,343	11/14/2003	James M. Lipton	54275.8016.US01	4070

7590 02/13/2007
Joseph Hamilton
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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/714,343

Applicant(s)

LIPTON, JAMES M.

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5 sheets.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Art Unit: 1654

1. A signed copy of the preliminary amendment originally filed on June 30, 2004 was received on November 15, 2006. A second preliminary amendment was filed on February 21, 2006. Where the same specification paragraph or claim is amended in both preliminary amendments, the second preliminary amendment filed February 21, 2006 represents the most recent version of the specification paragraph or claim.
2. The Sequence Listing filed February 21, 2006 has been approved by STIC for matters of form.
3. The preliminary amendments filed November 15, 2006 and February 21, 2006, and the Sequence Listing filed February 21, 2006, are objected to under 35 U.S.C. 132(a) because they introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The changes to the specification whereby "DNle" has been changed to "DNal" constitute new matter. See, e.g., paragraphs [0027], [0032], [0035], [0058], and [0065], and Table 1. These two amino acids are patentably distinct from one another, and a change from one to the other is new matter. Those sequences recited in the Sequence Listing which comprise DNal residues, e.g., SEQ ID NOS:2, 3, 12, 23, 27, 28, 30, 32, 37, 38, 42, 44, and 46 are new matter. The original disclosure of the invention does not include any disclosure of peptides comprising a DNal residue. Applicants have not indicated where the original disclosure of the invention supports the newly recited disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Art Unit: 1654

4. The disclosure is objected to because of the following informalities: At paragraph [0057], line 12, a SEQ ID NO needs to be inserted after the tetrapeptide sequence. See 37 CFR 1.821(d).

Appropriate correction is required.

5. Once a final form for the specification is agreed upon between the examiner and Applicant, the examiner will require a substitute specification under 37 CFR 1.125 to be filed in order to aid the printer in printing any patent which issues based upon this application.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 17, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the claimed amino acids which include DNal (i.e., D-naphthylalanine) residues. See claims 2, 3, 17, and 20. The original disclosure of the invention recited DNle (i.e., D-norleucine) residues at the corresponding positions. DNle is patentably distinct from DNal, and the former does not provide written descriptive support for the latter. Applicant has not indicated where the original disclosure of the invention supports the new claim limitations.

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Art Unit: 1654

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 7, 8, 11, 14-16, 18, and 19 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 4, 5, 8-11, 13, and 14 of prior U.S. Patent No. 7,135,548.

This is a double patenting rejection.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s): See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 4, 5, 9, 10, 12, and 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,135,548. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '548 patent clearly anticipate the instant claims.

10. Claim 4 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,115,574. Although the conflicting

claims are not identical, they are not patentably distinct from each other because the claims of the '574 patent anticipate instant claim 4. In particular, the peptide of SEQ ID NO:2 of the '574 patent meets the requirements of Applicant's SEQ ID NO:4.

11. Claim 4 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,969,590. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '590 patent anticipate instant claim 4. In particular, the peptide of SEQ ID NO:3 of the '590 patent meets the requirements of Applicant's SEQ ID NO:4.

12. Claim 4 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,939,846. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '846 patent anticipate instant claim 4. In particular, the peptide of SEQ ID NO:3 of the '846 patent meets the requirements of Applicant's SEQ ID NO:4.

13. Claim 4 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,887,846. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '846 patent anticipate instant claim 4. In particular, the peptide of SEQ ID NO:3 of the '846 patent meets the requirements of Applicant's SEQ ID NO:4.

14. Claim 4 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,780,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of

the '838 patent anticipate instant claim 4. In particular, the peptide of SEQ ID NO:3 of the '838 patent meets the requirements of Applicant's SEQ ID NO:4.

15. Claim 4 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 10/845,778.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '778 application anticipate instant claim 4. In particular, the peptide of SEQ ID NO:2 of the '778 application meets the requirements of Applicant's SEQ ID NO:4.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claim 4 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/853,902.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the '902 application anticipates instant claim 4. In particular, the peptide of SEQ ID NO:3 of the '902 application meets the requirements of Applicant's SEQ ID NO:4.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claim 4 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 3 of copending Application No. 10/442,683.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '683 application anticipate instant claim 4. In particular, the peptide of SEQ ID NO:2 of the '683 application meets the requirements of Applicant's SEQ ID NO:4.

Art Unit: 1654

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Instant claims 1, 4, 5, 7-12, 14-16, 18, and 19 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of application serial no. 60/426,929 because the '929 application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

Instant claims 2, 3, 17, and 20 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application serial no. 60/426,929 because the '929 application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the peptides comprising a DNal residue at position 2. Note that the DNle residue disclosed in the '929 application and the DNal residue claimed in the instant application have patentably distinct structures.

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by Catania et al (U.S. Patent Application Publication 2004/0033955). Catania et al teach a peptide HFRWGKPV (see, e.g., claim 2) which satisfies the requirements of Applicant's SEQ ID NO:4. Catania et al's peptide is disclosed in provisional application 60/382,887 (see, e.g., claim 2), and accordingly

Art Unit: 1654

Catania et al's disclosure of this peptide is entitled under 35 U.S.C. 119(e) to the benefit of the filing date of the provisional application in which this peptide is disclosed. Because the inventorship of Catania et al is different than the inventorship of the instant application, Catania et al's disclosure of this peptide is available as prior art against instant claim 4 under 35 U.S.C. 102(e).

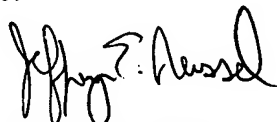
21. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 00/59527. The WO Patent Application '527 at claim 6 teaches an octapeptide which satisfies Applicant's claimed formulas. For instant claim 4, the WO Patent Application '527 teaches Pro as corresponding to Applicant's X3.

22. Claims 2, 3, 17, and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by the Grieco et al article (J. Med. Chem., Vol. 46, pages 850-855). The Grieco et al article in Table 3 teaches peptide 2, which anticipates the peptides recited in claim 2; peptides 19 and 20, which anticipate the peptides recited in claim 3; peptides 23, 24, and 26, which anticipate the peptides recited in claim 17; and peptide 14, which anticipates the peptides recited in claim 20.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

February 6, 2007